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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

GABEL, GAILENE

ART UNIT PAPER NUMBER

1641

DATE MAILED: 03/13/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/268,437

Applicant(s)

DING ET AL.

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/28/01 has been entered.

Request for Reconsideration

2. Applicant's response filed 12/28/01 in Paper No. 17 is acknowledged and has been entered. Currently, claims 1-5 and 10 are pending and under examination.

Rejection Withdrawn

Claim Rejections - 35 USC § 112/102

3. In light of Applicant's argument, the rejection of claims 1-5 and 10 under 35 U.S.C. 112, first paragraph, as lacking literal support in the specification for the recitation of "no active mixing", is hereby, withdrawn.

Specifically for the record, at page 5, lines 3-9, Applicant discloses that diffusion during assay in the device takes place in a quiescent solution. At page 12, lines 5-13 of the specification, Applicant also discloses that "convection must be minimized. ...

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molecules travel in a quiescent solution ...". Convection is defined as fluid motion caused by external force, i.e. gravity or current circulation; thus, providing support for no active or mechanical mixing, i.e. by stirrers. Further in lines 15-16, Applicant discloses that "Fickian diffusion is the only mode of mass transport (of molecules)."

4. In light of Applicant's argument, the rejection of claims 1-5 and 10 under 35 U.S.C. 102(e) as being anticipated by Meyerhoff et al. (US 5,981,203), is hereby, withdrawn.

Rejection Maintained

Claim Rejections - 35 USC § 112

5. Claims 1-5 and 10 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, for reason of record.

Specifically, the specification does not provide literal support for the recitation of "analyte binding areas comprise liquid impervious sheets" in claim 10. Applicant points to the specification at page 11, line 15, which discloses use of "polystyrene sheet" but fails to provide literal support for such a recitation set forth in claim 10. Furthermore, none of the originally filed claims recited the limitation in question. Recitation of claim limitation lacking support in the specification or originally filed claims constitutes new matter.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-5 and 10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for liquid impervious sheets such as polystyrene, silicon, or Teflon sheets, does not reasonably provide enablement for any other liquid impervious sheets such as metal. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

As set forth in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988), the factors to be considered in determining whether a claimed invention is enabled throughout its scope without undue experimentation include the quantity of the experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of prior art, the relative skill of those in the art, and the breadth of the claims.

As to the surface in the claimed cell of the device, the direction and guidance in the specification is notably limited to liquid impervious sheets such as polystyrene, silicon, and Teflon. The working examples are, likewise, limited to polystyrene sheets. While Figure 2 provides sufficient guidance and direction for selection and use of solid

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surfaces or substrates such as polystyrene, silicon, and Teflon for example, which are liquid impervious, it does not teach or suggest how to make and use alternative solid surfaces or substrates such as treated wood, metal, or crystal. Alternatively, treated wood which is solid by nature as set forth in Figure 2, is not necessarily liquid impervious. Therefore, based on this limited disclosure and direction, one of the skill in the art would not know how to make and use alternative liquid impervious sheets which comprise solid surfaces such as metal or quartz, for solid surface or substrate in the instant electrochemical device, without undue experimentation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. Claims 1-5 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Wohlstadter et al. (US 6,066,448).

Wohlstadter et al. disclose an electrochemical device comprising a cell or a plurality of cells adapted to hold a sample wherein the cell has a surface (support) having a plurality of analyte binding areas (discrete binding domains) each having a different analyte binding substrate. Wohlstadter et al. further disclose the cell including a plurality of working electrodes each adjacent to an analyte binding area separate from

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another binding area by a distance, i.e. binding domains spatially aligned and in proximity to a plurality of electrodes, and further including reference electrodes, sensing electrodes, and auxiliary electrode (see column 42, lines 36-49, column 9, lines 53-65, and column 11, line 56 bridging to column 12, line 31). The analyte binding areas are localized by coating different binding affinities on different binding substrates, i.e. binding reagents, that bind to at least one analyte of interest (see column 19, lines 25-37). The binding substrates are selected so as to have a desired binding specificity which includes proteins, antibodies, antigens, receptors, epitopes, etc. (see column 20, lines 30-67). The substrates each may have a different antigens or different antibodies (see columns 21-22). The analyte binding areas are supported by liquid impervious sheets such as silicon, glass, plastic, and carbon fibrils including ceramics and Teflon (see columns 11-13).

Response to Arguments

8. Applicant's arguments filed 12/28/2001 have been fully considered but they are not persuasive.

A) Applicant argues that liquid impervious sheets, such as polystyrene, are fully supported by the depiction of a cross-section of a solid substrate in Figure 12 in which unbroken slanted lines are used, which clearly indicate that the support is solid and is liquid-impervious. According to Applicant, since the structure sets forth a solid support, a recitation of a function, i.e. impermeable to liquid, can be incorporated into a claim without introducing new matter.

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In response, a solid support as set forth by Applicant's drawing in Figure 12 does not fully encompass a function as being solely liquid impermeable. Specifically, not all solid supports are impervious to liquid. See paragraph No. 6 and discussion thereafter.

9. Applicant's arguments with respect to claims 1-5 and 10 as being anticipated by Meyerhoff have been considered and the rejection has been withdrawn. However, the arguments to that regard are moot in view of the new ground of rejection.

10. No claims are allowed.

Remarks

11. Prior art made of record are not relied upon but considered pertinent to the applicants' disclosure:

Wohlstadter et al. (US 6,140,045) disclose multi-array, multi-specific, electrochemiluminescence testing.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gail Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday to Thursday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays from 7:00 AM to 3:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gail Gabel
Patent Examiner
Group 1641

G. Gabel
3/29/02

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03/11/02